# 2018 Year in Review



# Banking for Life

### A message from the Executive Director

Dear friends,

By definition, cord blood contains stem cells which can be used to treat hematopoietic and genetic disorders. By experience, we understand that cord blood and the impact it has on someone with a life-threatening disease, is much more.

We understand this because of the great work we witness each day across the country. We invite you to read through the Year in Review to learn more about the Cleveland Cord Blood Center's (CCBC) incredible progress in 2018. Of note is the opening of our state-of-the-art Cell Therapy Incubator (CTI), and the new approaches being tested by our research scientists. The newly opened CTI lab will help to fill critical gaps for academic research teams and small biotechnology companies working on additional treatment options for patients in need.

Meanwhile, our research teams continue innovative research in the development of stem cell treatments to address unmet medical needs in patients suffering from Parkinson's disease, diabetes, and HIV/AIDS. We strive for even more success in the year ahead.

Save a Cord. Save a Life.

Marcie R. Finney, M.S. **Executive Director** 

## About the Cleveland Cord Blood Center

The Abraham J. and Phyllis Katz Cord Blood Foundation, dba Cleveland Cord Blood Center, is a non-profit organization that collects, processes, stores and distributes stem cell-rich umbilical cord blood, and conducts innovative medical research in cord blood cellular therapeutics. The cord blood, usually discarded at birth, is used for the treatment of deadly blood cancers and other life-threatening illnesses, and for medical research. As a non-controversial source of stem cells, cord blood is collected from umbilical cords after delivery of full-term, healthy infants.

Established in 2008, CCBC has been issued a biologics license from the U.S. Food and Drug Administration (FDA), is accredited by the Foundation for Accreditation of Cellular Therapy (FACT) and the American Association of Blood Banks (AABB), is designated as a Health Resources and Services Administration (HRSA) contractor, and is a member bank of the National Marrow Donor Program (NMDP).

In the rapidly advancing cellular therapy industry, Cleveland Cord Blood Center's new Cell Therapy Incubator, opened in 2018, is designed to help move innovative cellular therapy products from Research & Development to FDA approval. Services are designed to help developers of cell-based therapies in regenerative medicine reach the critical milestones needed to accomplish clinical proof of concept for safety and efficacy of dosing, dose formulation and regimens.



### Leading a team dedicated to untapping cord blood's lifesaving potential

Cleveland Cord Blood Center Founder and Medical Director Mary J. Laughlin, M.D. performed one of the world's first successful umbilical cord blood transplants in an adult leukemia patient in 1995. She has performed over 150 cord blood transplants since then, and remains on the forefront of umbilical cord blood banking and research.

Since founding the public cord blood bank in 2008, she has fostered a culture of caring that "goes to the heart" of Cleveland Cord Blood Center's dedication to transplant recipients, donating parents, researchers, obstetricians and nurses, and transplant physicians.

"Quality is paramount, from active engagement with obstetricians and nurses who directly link their roles with donating mothers to the lifesaving work of the cord blood they collect, to the processing and storage of higher dose stem cell units for clinically banked units," said Dr. Laughlin. "The Cleveland Cord Blood Center is a leading provider of quality stem cell units for transplant, as well as a major provider of mixed race units for transplants and research."

The Cleveland Cord Blood Center team's work is grounded in a shared vision to help save lives. "CCBC researchers are exploring cord blood treatments for a variety of medical applications, ranging from wound healing and Type 1 Diabetes to Parkinson's disease. The new Cell Therapy Incubator will help take novel cell therapies from proof of concept through clinical manufacturing," said Dr. Laughlin.

"Our focus is to apply our experience and successes with cord blood stem cells to an international effort dedicated to the realization of the tremendous potential of umbilical cord blood in saving lives," she concluded.





# Cord Blood Donations Support Lifesaving Work

## **New Cell Therapy Incubator launched**

The new, state-of-the-art Cleveland Cord Blood Center Cell Therapy Incubator (CTI) opened in December 2018. The new facility is designed to support Good Manufacturing Practice (GMP) compliance with the goal to advance innovative cellular therapy products from Research & Development to FDA approval. CTI can also serve as a bridge to commercialization of early stage cellular therapy products.

"With critical know-how in all stages of Research & Development, and (pre)-clinical development, and the facility and staff to support customers, CTI leverages the Cleveland Cord Blood Center's capabilities, demonstrated guality, and regulatory and manufacturing expertise to create a much-needed independent laboratory for the cellular therapy industry," said CCBC Cord Blood Bank Director Wouter Van't Hof.

CTI helps fill a critical gap for academic research teams and small biotechnology companies that typically do not have the resources to justify large capital investments for a facility of this type. "We see the work we do can for customers ultimately translating into treating more patients by moving cellular therapy products from Research & Development to FDA approval," noted Executive Director Marcie Finney.



### **Cord blood donation supports** treatment, research

When their son Ethan was born at Kaiser Permanente San Francisco Medical Center in 2017, Rebekah Drechsel and her husband, Anthony, didn't hesitate to donate. Instead of treating cord blood as medical waste, she recognized the donation as "a way to possibly save another person's life."

Drechsel understood that the donation could also be used in research. "Cures come from research, and scientific advances in research may not be made without such donations," Drechsel said.

Drechsel, who is of European descent, and her husband being of Mexican heritage, recognized the importance of donors from mixed heritage. Ethan's cord blood contributes to helping meet the increasing demand for mixed race donations, an area of particular focus of the Cleveland Cord Blood Center.

"At the end of the day, the extent to which you can broaden and diversify cord blood contributions, you're helping to increase the possibility of a match and a successful treatment," she added. "If it's something you can do to save a life, that's an amazing thing. Why not go for it?"





Together, umbilical cord blood donated by parents at five partner hospitals reached a total of 6,971 cord blood units.

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**2018 YEAR IN REVIEW** 



# Cord Blood Distributed Throughout the U.S., Around the World through 2018

### CCBC Cord Blood Distributions Across the United States (2008 to 2018)



### CCBC Cord Blood Distributions Across the Globe (2008 to 2018)



# A Gift of Life and Hope

## Donation can make an incredible difference in someone's life

Rochelle Grenier, a 34-year-old single mother of a teenage daughter from Lebanon, Conn., was diagnosed with stage IV Non-Hodgkin's lymphoma in 2003. As other treatment options failed, her doctors searched the bone marrow registries to find that there were no sufficiently matched adult stem cell donors available. She then learned of a double umbilical cord blood stem cell transplant clinical trial that she ultimately participated in.

On April 26, 2006, the day she received her cord blood transplant, Grenier's friend and mother sang "Happy Birthday" to her in celebration of the next chapter of her life.

Grenier passionately encourages expectant mothers to donate their babies' cord blood whenever the opportunity arises. "For every mother about to give birth, I like to let them know that when they donate their babies' cord blood, there will be a little piece of their beautiful child helping make an incredible difference in someone else's life. The most incredible gift you can give someone is the gift of life," she said.

### **Dual stem cell therapy explored to treat Parkinson's disease**



Parkinson's disease is a debilitating neurodegenerative disease affecting nearly 1 million Americans, with a notably higher estimated prevalence in the Midwest. The Cleveland Cord Blood Center Research and Development Laboratory, under lead researcher Daniel

Zwick, Ph.D., is exploring an innovative, new therapeutic approach using two cord blood stem cell populations. CCBC researchers hypothesize that a dual stem cell therapy, consisting of mesenchymal stem cells (MSC) and hematopoietic stem cells (HSC), both derived from a



Units Received Per Day

5

About 2018 Cord Blood

**Recipients and Donors** 

• Recipients ranged in age from

Race of units distributed for

transplant: 56% Caucasian; 15% African American;

internationally - 16%

Myelodysplastic/

13% multi-race; 10% Hispanic;

• Units collected have been used to treat a variety of diseases

Non-Hodgkin lymphoma

Severe aplastic anemia

myeloproliferative disorders

Disorders of the immune system

Inherited disorders of metabolism

Units distributed: in the U.S – 84%;

Acute lymphoblastic leukemia (ALL)

Acute myelogenous leukemia (AML)

under 1 to 72

7% Asian

including:



single cord blood graft, will have additive effects that benefit Parkinson's disease therapy.

In pre-clinical studies, preliminary results have shown that dual stem cell treatment dramatically enhances neuro-regeneration. Following proof of concept work, the research team plans to complete clinical manufacturing steps in CCBC's FDA-approved facility to rapidly transition their approach to a Phase I safety clinical trial in patients who have failed standard medical therapy and are undergoing electrode placement for planned deep brain stimulation.

Earlier work by Dr. Mary J. Laughlin, founder and medical director of the Cleveland Cord Blood Center, serves as a foundation for the organization's Parkinson's disease research.

## **Cleveland Cord Blood Center 2008 to 2018**





**Countries Reached** 



Supported by The Abraham J. and Phyllis Katz Foundation and Dr. Donald J. and Ruth Weber Goodman Philanthropic Fund

### Leadership

Mary J. Laughlin, M.D. Founder and Medical Director

Marcie R. Finney, M.S., MBA Executive Director

Wouter J. Van't Hof, Ph.D. Cord Blood Bank Director/ Processing Facility Director

Lisa Phillips Johnson, B.S. Quality and Regulatory Affairs Director

### **Board of Directors**

Bruce Goodman Board Chair Alex Katz Mary J. Laughlin, M.D. Pablo Rubinstein, M.D. David Woolf

**Cleveland Cord Blood Center** 25001 Emery Road Suite 150 Cleveland, Ohio 44128 Phone: 216-896-0360

866-922-3668



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